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Ivan Faul

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EXAMINER

FERNANDEZ, KATHERINE L

ART UNIT

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3768

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/808,459	Applicant(s) FAUL, IVAN	
	Examiner KATHERINE L. FERNANDEZ	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Claim Objections

1. Claims 1, 11 and 13-14 are objected to because of the following informalities:

Claim 1 recites the limitation "said preprogrammed cutting path" in line 19.

There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "said receiver means" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "said receiver" in two occurrences in lines 1-

3. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "said receiver" in line 1 and "said resection, or rendering necrotic operation" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillstead et al. (US Patent No. 2004/0039312) in view of Schulz et al. (US Patent No. 5,907,395).

Hillstead et al. disclose a system for improving the accuracy of preprogrammed surgery on a body having an inside portion that is in need of said surgery and an outside portion that is moveable during said surgery, comprising: a plurality of markers, that are adapted to emit a corresponding plurality of signals, and that are adapted to be disposed on said moveable outside portion of said body proximate to said inside portion in need of said surgery (pg. 3, paragraph [0058]; pg. 4, paragraph [0066]; pg. 6, paragraphs [0086]-[0087], [0090]); means for tracking the movement of said outside portion of said body (pg. 3, paragraph [0058]; pg. 4, paragraph [0066]; pg. 6, paragraphs [0086]-[0087]); means to identify and map said inside portion of said body that is intended to be subjected to surgery (pg. 3, paragraphs [0054]-[0060]); means to preprogram a treatment path adapted to be followed by treatment means, wherein the treatment means comprises high energy radiation (i.e. HIFU) sufficient to render said inside portion of said body necrotic (pg. 4, paragraphs [0061]-[0062]; pg. 2, paragraphs [0022]-[0026]); means to integrate said tracked movements with said preprogrammed treatment path to form a modified treatment path (pg. 4, paragraphs [0066]-[0067]; pg. 5, paragraph [0071]; pg. 6, paragraphs [0090]-[0091]); means to cause said treatment means to treat said inside portion of said body along said modified treatment path while substantially preventing said treatment means from departing from said modified treatment path to any substantial extent (pg. 6, paragraphs [0090]-[0091]). The treatment means can be adapted to be operated without benefit of a surgeon (pg. 4, paragraph [0066]).

However, although they do disclose that the movement of the outside portion of said body is tracked (pg. 3, paragraph [0058]; pg. 4, paragraph [0066]; pg. 6, paragraphs [0086]-[0087]; [0090]), they do not specifically disclose that the markers, respectively, comprise a disposable support element that is substantially unaffected by bodily sections, adapted to be attached to an outside portion of said body, and a signal emitter (i.e. LED) operatively associated with said support element, means for causing said emitters to respectively emit signals under conditions sufficient to differentiate which emitter is sending each of said signals, respectively, wherein emitted signals are adapted to enable tracking the movements of said moveable outside portion of said body. They further do not disclose that said LEDs are disposed remote from said body and further comprises at least one fiber optic cable having an end that is operatively associated with each of said LEDs at a location remote from said body and having another end that is adapted to be substantially fixedly disposed on said moveable outside portion of said body proximate to said inside portion of said body in need of said treatment. They further do not specifically disclose that the LED emissions are at least one selected from the group consisting of emissions having wavelengths in the visible red region and emissions having wavelengths in the infrared region. They further do not disclose that the emissions comprise visible wavelengths and optical fibers comprise plastic material. They further do not disclose that their system comprises receiver means, which comprises an array of cameras, disposed remote from said body and positioned to be adapted to receive signals from said emitters, respectively or that the emitters are in line

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of sight with said receiver means so that said signals emitted from said emitters are adapted to be received by said receiver.

Schulz et al. disclose an effective way to produce substantially point source emissions of electromagnetic ray energy from locations on objects to be tracked in three dimensional space by an electro-optical location determination system (column 5, lines 18-23). They disclose that their emitters can be attached to any object being tracked, such as a patient (column 5, lines 35-48). Their invention consists of an optical fiber (24) having an emitter (24) attached at one end and a laser diode (20) (i.e. special type of LED) attached at the other end (column 6, lines 18-44; see Figure 2). The emitter end of the optical fiber is attached to the object (12) being tracked and the laser diode end is at a location remote from the object (column 6, lines 18-44; see Figure 2). Their invention further comprises an electro-optical sensor assembly (i.e. camera array) that senses the emission and returns raw data of the location of each emitter (column 7, lines 26-60; column 8, lines 9-20). The laser diodes can be located individually and uniquely identified (column 7, line 62-column 8, line 8). The LED emissions can be either in the infrared region or can comprise visible wavelengths (column 3, lines 50-57; column 13, instant claims 27 and 28). They further disclose that the optical fibers can be made of plastic (column 9, lines 5-7). Although they do not specifically disclose that the optical fibers can be made from glass, it is well known in the art that optical fibers can be made of glass and therefore it would have been within the skill of one of ordinary skill in the art to use a widely available and well known material, such as glass, for the optical

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fiber. As can be seen in Figure 1, the camera array (30) can be disposed remote from the object being tracked and positioned to receive signals from said emitters, respectively (column 8, lines 9-27). Further, as can be seen in Figures 1 and 2, the LEDs and the receiver can be positioned to be disposed at an angle of about 45 degrees with respect to the place where said body will be placed for rendering a necrotic operation (see Figures 1 and 2). As can be seen in Figures 4, 5 and 7, said emitters (26) are operatively associated with wedge shaped member and wherein the combination of emitters and said wedge shaped members, respectively, are adapted to dispose said emitters in line of sight with said receiver means and the wedge shaped members have adjustable angles. Their system includes means to control the frequency of emissions from said emitters at a rate such that changes in the location of said moving outside surface are reflected in the determined positions and orientations of said markers as a function of time (column 7, line 62-column 8, line 8). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Hillstead et al. to include the above discussed limitations, as Hillstead et al. require marker means for tracking the movement of the outside portion of the body and Schulz et al. disclose means for tracking an object by using optical fibers with LEDs attached to one end located remotely from the body and the other end attached to the object being tracked which provides more more accurate determination of the position and orientation of object being tracked (see abstract).

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4. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hillstead et al. in view of Schulz et al. as applied to claim 12 above, and further in view of Makin et al. (US Pub No. 2003/0040698).

As discussed above, the above combined references meet the limitations of claim 12. However, they do not specifically disclose that the inside portion of said body comprises at least one stone in need of removal and further comprising said ultrasound radiation being of sufficient strength to be adapted to break up said stone into pieces that are small enough to be passed. Hillstead et al. do disclose that HIFU is used for the destruction of the inside portion that is in need of surgery (see abstract). Makin et al. disclose that HIFU is currently used for lithotripsy procedures where kidney stones are broken into small pieces by ultrasonic shock waves generated through ultrasound energy focused into the body (pg. 1, paragraph [0005]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of the above combined references to have the inside portion of said body comprise at least one stone and use ultrasound radiation of sufficient strength to break up the stone into pieces, as the above combined references teach the use of HIFU for the destruction of tissue and Makin teaches that HIFU can be used for the destruction of kidney stones.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose

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telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768